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10/810,762	03/26/2004	Jeffrey H. Baxter	7357US01	9087

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Ross Products Division
Abbott Laboratories
625 Cleveland Avenue
Columbus, OH 43215

EXAMINER

ROYDS, LESLIE A

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1614

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,762	Applicant(s) BAXTER ET AL.	
	Examiner Leslie A. Royds	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-20 is/are rejected.
- 7) ☒ Claim(s) 9, 16 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-21 are presented for examination.

Applicant's Amendment filed September 24, 2007 has been received and entered into the present application.

Claims 1-21 remain pending. Claims 9-20 are under examination and claims 1-8 and 21 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

Applicant's arguments, filed September 24, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objections to the Claims (New Grounds of Objection)

Claim 9 is objected to for failing to define the acronym "HMB" at its first occurrence.

Claim 16 is objected to for failing to define the acronym "FOS" at its first occurrence.

Claim 18 is objected to for improper periods within the subparts of the claim. Proper form of claims dictates that only one period should be contained with a claim (i.e., at the end of the claim), unless it is used to denote a decimal point.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1614

Claims 9-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claim 9 is directed to a composition comprising (a) beta-hydroxy-beta-methylbutyrate (hereinafter “HMB”), its salts, metabolites or derivatives thereof; (b) carnitine; and (c) an amino nitrogen source enriched with large neutral amino acids; and where said composition is substantially lacking in free amino acids.

In particular, the specification and claims as originally filed fail to provide adequate written support for (1) the genus of metabolites or derivatives of HMB (claim 9) or (2) the amino nitrogen source enriched with large neutral amino acids (claim 9).

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP at §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, “not a mere wish or plan for obtaining the claimed chemical invention.” *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office (“PTO”) Guidelines for *Examination of Patent Applications* under the 35 U.S.C. 112.1 “Written Description” Requirement (“*Guidelines*”), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by “showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics,” including, *inter alia*, “functional characteristics when coupled with a known or disclosed correlation between function and structure...” *Enzo Biochem v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual

Art Unit: 1614

context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Regarding the Genus of Metabolites or Derivatives of HMB (Claims 9, 11-17 and 19-20):

Applicant discloses at p.13, third full paragraph, of the instant specification, "The term 'HMB' refers to the compound having the foregoing chemical formula, in both its free acid and salt forms, metabolites and derivatives thereof. While any suitable form of HMB can be used within the context of the present invention, preferably, HMB is selected from the group consisting of a free acid, a salt, an ester, and a lactone; more preferably, HMB is a salt." Applicant discloses that a preferable ester form is methyl or ethyl ester and a preferable lactone form is an isovaleryl lactone (p.14, first and second full paragraphs).

Applicant has failed to provide sufficient written description to support the use of HMB metabolites or HMB derivatives, aside from the specific ester and lactone forms described (i.e., methyl ester, ethyl ester or isovaleryl lactone). In fact, the present disclosure fails to recite any structural characteristics, chemical formula, name(s) or physical characteristics, aside from the specific species exemplified, that would provide adequate written description of the metabolites or derivatives of HMB that Applicant was actually in possession of, and intended to be used within the context of the present invention, at the time of the present invention. The specification fails to contain any limiting definition or any structural, chemical or physical characteristics of these metabolite or derivative forms (aside, of course, from those that are specifically exemplified; i.e., HMB methyl ester, HMB ethyl ester, or the isovaleryl lactone form of HMB) such that one of ordinary skill in the art would have been able to readily identify the scope of those compounds and still be considered a "metabolite" or "derivative" as intended by Applicant.

While it may be construed that the fact that the compound is based upon, or derived from, the parent HMB structure implies some sort of chemical or structural characteristics sufficient to fulfill the

Art Unit: 1614

written description requirement of 35 U.S.C. 112, first paragraph, it is herein noted that Applicant has failed to describe in any certain terms the degree of derivation or similarity that a compound may have from HMB *per se* and still be considered a metabolite or derivative for use in the invention as presently claimed. The mere fact that the only chemical or structural characteristic of the compound is that it is a metabolite or derivative of HMB, wherein the degree of metabolization, similarity or derivative from HMB is herein undefined in the accompanying specification, is not sufficient to provide an adequate description of the genus of compounds intended by Applicant for use in the present invention. In the absence of such description, Applicant's limitation directed to metabolite or derivative forms of HMB is not sufficiently supported by the present disclosure in such a way as to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of the entire genus of HMB metabolites or derivatives as presently claimed (claim 9).

Accordingly, for these reasons, the claims are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Regarding the Amino Nitrogen Source Enriched with Large Neutral AA (Claims 9-20):

Applicant discloses in the first full paragraph at p.7 of the instant specification, "In yet another embodiment, HMB may be added to food products comprising a source of amino-nitrogen enriched with large neutral amino acids such as leucine, isoleucine, valine, tyrosine, threonine and phenylalanine and substantially lacking in free amino acids." Applicant additionally discloses at p.17-18, "Suitable protein sources include, but not limited to, milk, whey and whey fractions, soy, rice, meat (e.g., beef), animal and

Art Unit: 1614

vegetable (e.g., pea, potato), egg (egg albumin), gelatin and fish. Suitable intact protein sources include, but are not limited to, soy based, milk based, casein protein, whey protein, rice protein, beef collagen, pea protein, potato protein, and mixtures thereof. Optionally, the intact protein source is enriched in large neutral amino acids (LNAA) comprising valine, isoleucine, leucine, threonine, tyrosine and phenylalanine. Typically, about 40% of casein, whey and soy protein sources are large neutral amino acids...Typically, the meal replacement is formulated with a protein source that will deliver about 1 to 25 gm of LNAA per day, preferably from about 1 to 20 gm of LNAA per day, more preferably from about 4 to 20 gm of LNAA per day. As an example, a meal replacement consumed 3 times a day that contains a protein comprising 4.8 gm LNAA will deliver 14.4 gm LNAA per day.”

Applicant has failed to provide sufficient written description of the “amino nitrogen source enriched with large neutral amino acids”. In fact, the present disclosure fails to recite any structural characteristics, chemical formula, name(s) or physical characteristics, aside from the fact that the source is “enriched” with large neutral amino acids (e.g., leucine, isoleucine, valine, etc.), that would identify, and, thus, provide adequate written description of, the “amino nitrogen source” that Applicant was actually in possession of, and intended to be used within the context of the present invention, at the time of the present invention. The specification fails to contain any definition, limiting or otherwise, or any structural, chemical or physical characteristics of this source such that one of ordinary skill in the art would have been able to readily identify the scope of those components that would be considered an “amino nitrogen source enriched with large neutral amino acids” as intended by Applicant.

Applicant is reminded that, “Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention.” Please reference MPEP §2163. Applicant has clearly failed to

Art Unit: 1614

describe, or establish that the state of the art was sufficiently well-developed that one of ordinary skill in the art at the time of the invention would have immediately envisaged, the “amino nitrogen source(s)” in possession of Applicant at the time of the invention for use within the context of the present invention. Furthermore, Applicant discusses “protein sources” and “intact protein sources” at p.17-18 of the instant specification, stating that each may be enriched with large neutral amino acids, such as, e.g., valine, isoleucine, leucine, threonine, tyrosine and phenylalanine, but fails to describe whether said “protein sources” or “intact protein sources” are, in fact, amino nitrogen sources as instantly claimed such that one of ordinary skill in the art at the time of the invention would have recognized any one or more of these protein sources to be useful as the amino nitrogen source of the presently claimed invention.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of an “amino nitrogen source enriched with large neutral amino acids” (claim 9).

Accordingly, for these reasons, the claims are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

For the purposes of examination, Applicant’s claimed “amino nitrogen source enriched with large neutral amino acids” will be interpreted to read upon any of the disclosed “protein sources” or “intact protein sources”.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1614

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 11-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood (U.S. Patent Application Publication No. 2004/0071825; Issued April 2004, Filed October 2002).

Lockwood teaches an agglomerated granular protein-rich nutritional supplement, prepared in an oral dosage unit that may be adsorbed directly on the tongue or dissolved in an aqueous liquid, such as water (p.5, para.[0032]), that comprises a mixture of edible nutritional food proteins, edible carbohydrates, edible fats, edible dietary vitamins and minerals, edible amino acids and edible plants extracts, wherein the edible nutritional food protein is, *inter alia*, whey proteins or soy proteins [i.e., meets Applicant's claimed "amino nitrogen source enriched with large neutral amino acids", particularly wherein the large neutral amino acids comprise at least 10% of the amino nitrogen source (claim 13), in view of the fact that this claimed source has been interpreted for examination as any one of the "protein sources" or "intact protein sources" defined at p.17-18 of the instant specification, which are defined as whey or soy protein, which each contain at least 40% by weight large neutral amino acids; see also Lockwood at p.5, para.[0033]]; the edible carbohydrate is, *inter alia*, fructooligosaccharides (p.5, para.[0033]); the edible fat is, *inter alia*, docosahexaenoic (DHA) or eicosapentaenoic acid (EPA) (p.5,

Art Unit: 1614

para.[0034]); the edible dietary vitamins and minerals are, *inter alia*, B- and B-complex vitamins, vitamin D, folic acid, calcium, iron, magnesium, etc. (p.5, para.[0034]); the edible amino acids are provided for individually or in combination and are defined as, *inter alia*, carnitine and HMB (p.5, para.[0035]). Lockwood discloses that the oral unit dosage form will contain approximately 56-78% by weight edible nutritional food proteins (p.5, para.[0040]); approximately 13-20% by weight edible carbohydrates (p.5, para.[0041]); less than 3% by weight edible fats (p.5, para.[0042]); approximately 0-2% by weight edible dietary vitamins and minerals (p.5, para.[0043]); approximately 0-27% by weight edible amino acids (p.5, para.[0044]); approximately 0-1% by weight edible plant extracts (p.5, para.[0045]). Lockwood further discloses that the composition may be used in women, male bodybuilders, children, adolescents and older adults (abstract).

For example, according to the proportions disclosed by Lockwood, a 100 g supplement would contain 56-78g edible nutritional food proteins, 13-20g edible carbohydrates, less than 3g edible fats, 0-2g vitamins and minerals, 0-27g edible amino acids, 0-1g plant extracts. This teaching clearly meets Applicant's instantly claimed limitations directed to (i) free amino acids comprise less than 0.4g/serving of the composition (claim 14), since Lockwood clearly provides for compositions that do not contain any additional free amino acids (see, e.g., p.5, para.[0035]) and (ii) at least 1g FOS (claim 16), since Lockwood provides for 13-20g carbohydrates.

Though Lockwood provides for, e.g., 0-27% by weight amino acids, Lockwood fails to provide, specifically, for the use of carnitine in an amount of less than 2g/serving (claim 15).

However, the determination of the optimum dosage amount of carnitine (claim 15) would have been a matter well within the purview of, and *prima facie* obvious to, one of ordinary skill in the art at the time of the invention. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics

Art Unit: 1614

and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the amount that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed dosage amount is not seen to be inconsistent with that which would have been determined by, and well within the routine skill of, the skilled artisan.

Additionally, the concentration of the active ingredient is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

While the reference may not be anticipatory insofar as one must “pick and choose” from various lists of nutritional proteins, carbohydrates, fats and amino acids, it remains that would have been obvious to a person skilled in the relevant art, in a self-evident manner, to have selected those particular components detailed *supra* from the list of possible nutritional proteins, carbohydrates, fats and amino acids that may be employed in the disclosed composition to arrive at a composition comprising components identical to those instantly claimed. This skilled person would have been motivated to do so by the unambiguous disclosure of each particular species of component individually and alternatively as equivalents for each of the nutritional protein, carbohydrate, fat and amino acid components. This conclusion is supported by the fact that it has long been held in patent prosecution that a reference should be considered as expansively as is reasonably possible in determining the *full* scope of the contents within its four corners.

Claims 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood (U.S. Patent Application Publication No. 2004/0071825; Issued April 2004, Filed October 2002) in view of Nissen (U.S. Patent No. 6,103,764; 2000).

Art Unit: 1614

Lockwood as applied above in view of the following additional remarks:

Further, if one were to reconstitute a 100 g supplement in one liter of water, the composition of Lockwood would also meet Applicant's instantly claimed limitations directed to (i) at least 1g/L omega-3 fatty acids (claim 18), since Lockwood clearly provides for the use of, *inter alia*, DHA or EPA, in an amount of less than 3g (see, e.g., p.5, para.[0042]) and (ii) from about 1-25 g/L FOS (see, e.g., p.5, para.[0041]), since Lockwood clearly provides for the use of, *inter alia*, fructooligosaccharides in an amount of 13-20g.

Lockwood fails to teach the use of salts of HMB (claims 10 or 18) or the use of, specifically, about 2-10g/L calcium HMB with about 1-8g/L carnitine (claim 18).

Nissen teaches salts of HMB that are water-soluble or become water-soluble in the stomach and/or intestines, including sodium HMB, potassium HMB, magnesium HMB, chromium HMB and calcium HMB, as well as alkali metal HMB salts or alkaline earth metal HMB salts (col.2, 1.45-56). One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ a water-soluble salt of HMB, such as, *inter alia*, a calcium HMB salt, in the composition of Lockwood due to its water-solubility and, thus, amenability to reconstitution in solution to form a beverage. Furthermore, such a water-soluble salt would have been more readily absorbed across the lining of the stomach and/or intestines, thereby enhancing bioavailability and therapeutic effect.

Regarding the particular use of about 2-10g/L calcium HMB with about 1-8g/L carnitine (claim 18), the determination of the optimum dosage amounts of calcium HMB and carnitine (claim 18) would have been a matter well within the purview of, and *prima facie* obvious to, one of ordinary skill in the art at the time of the invention. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized

Art Unit: 1614

and whether the compound is administered as part of a drug combination. Thus, the amount that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed dosage amount is not seen to be inconsistent with that which would have been determined by, and well within the routine skill of, the skilled artisan.

Additionally, the concentration of the active ingredient is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Double Patenting (New Grounds of Rejection)

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 9-20 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 9-20 of copending U.S. Patent Application No. 11/025,466. This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent Application Publication No. 2001/0008641 to Krotzer ("Nutritionally Active Composition for Bodybuilding") and U.S. Patent No. 5,726,146 to Almada et al. ("Non-Steroidal, Anabolic Dietary Supplement and Method to Increase Lean Mass Without Linked Increased Fat Mass").

Art Unit: 1614

Rejection of claims 9-20 remains proper and is **maintained**.

Claims 1-8 and 21 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

March 6, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614